

Remarks

This is in response to the Office Action dated January 22, 2010.

In response to the objection, claims 7-9 each have been amended to recite "a" in place of "an" pre required by the examiner.

The pending claims are directed at a gas-treatment device for use with a tracheostomy tube having an elongate housing extending transversely of the tube and having a gas-treatment unit mounted in the housing. The claims go on to require the gas-treatment unit to be displaceable by rotation about an axis transverse to the tube to block or allow gas flow out of the end of the tube.

Claims 1-8 and 10 stand rejected as being obvious over Persson (US2002/0156527) and Geertsema (US6439233); and claim 9 stands rejected as being obvious over Persson and Geertsema in combination with Turnbull (US5647344).

Persson is in a similar field to that of the present invention and describes an HME that can be opened and closed to allow or prevent gas flow, as in the present invention. Where Persson differs from the present invention is that Persson does not have any transverse housing and is, instead, opened and closed by twisting the valve housing about the axis of the tracheostomy tube itself. The advantage the arrangement of the present invention achieves is that it enables a particular form of high efficiency HME element to be used, which takes the form of a coil of treated corrugated paper. Such an HME element would not fit readily within the coaxial arrangement described by Persson. The Examiner concedes that Persson is silent about any gas-treatment unit that is rotatable about an axis transverse to the axis of the tube (page 3, lines 13 and 14 of the Action).

Geertsema (US6439233) describes a very different form of device namely a tracheal stoma valve that is arranged to be opened and closed by patient breathing. The Examiner appears to have cited this patent because she believes that Geertsema's flap valve is

equivalent to the gas-treatment unit of the instant invention. It should however be pointed out firstly that the claims require "an elongate housing adapted for connection to the tube to extend generally transversely of the tube". There is no such housing in either Geertsema or Persson. The only housing in Geertsema is the valve housing 2 but this clearly extends axially of the tracheal tube, not transversely as required by the claims. Also, applicant would take issue with the Examiner that the valve flap 3 of Geertsema could correctly be regarded as a "gas treatment unit" as required by the claims since all it does is to partially block or enable flow of gas – the gas is not treated and does not change its character or properties in any way.

Moreover, the assertion by the examiner that Persson and Geertsema may be combinable based on the "predictable results" dicta by the *KSR* Court is believed to be misplaced for the following reasons. First, in *arguendo* that Persson and Geertsema are combinable, one result of such a combination could be the simple connection of the housing 2 of Geertsema in line with the Persson valve. This would not achieve any transverse housing or any gas-treatment unit that is displaceable by rotation about a transverse axis, as required by the claims. Another possible combination would be the replacement of the flexible membrane 20 valve arrangement of Persson with the pivoted flap valve 3 of Geertsema. This again would not achieve a device within the scope of the present invention. Simply put, it does not appear that any combination of Persson and Geertsema could possibly provide the gas treatment device defined by the pending claims.

It is furthermore submitted that the examiner has misconstrued the *KSR* "predictable result" test to support her obviousness rejection of the instant invention. Regress for the moment to the *KSR* decision where the underlying issue facing the Court was whether the addition of a sensor to an adjustable gas pedal to detect the pedal's position and transmit such to the computer controlling the throttle is obvious in light of the conventional cable-actuated throttle control, given that adjustable pedals and electronic pedal sensors for computer controlled throttles were known. (The accused infringer *KSR* had taken an adjustable mechanical pedal and added a modular sensor to it to make it compatible with

GMC light trucks that use engines with computer controlled throttles.) In holding that the patent by the patentee Teleflex to be obvious, the Court states:

Neither the enactment of §103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, \_\_\_\_\_ (2007). (Underlines added)

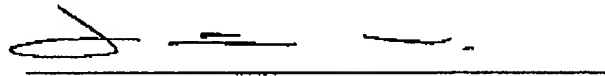
Thus, according to the Court, the predictable result in *KSR* arose due to the addition of an electronic sensor to detect the pivot angle of the gas pedal so that the detected positioning may be used in a computer controlled throttle as compared to the prior art mechanical throttle that is controlled by a linkage connected to and which actuation movement results from the pivotal movement of the gas pedal. Such substitution of an electronic control for a mechanical control linkage was deemed by the Court to be obvious.

Applicant submits that the present invention is different from the scenario whereby the KSR "predictable results" test would come into play. To wit, Persson and Geertsema teach devices that are structurally different and function differently. Moreover, as discussed above, different combinations of Persson and Geertsema would fail to meet the scope of the invention, as set forth in the claims. Furthermore, the assertion by the examiner that an additional valve such as that of Geertsema could be placed in Persson's

cone passage 18 most likely would result in a valve which operation and resulting function are different from those of the present invention, since such modified valve would have both the adjustable circular membrane 20 and the pivotable flap 3. And if the examiner were to argue that the membrane 20 of the Persson is being substituted by the flap 3 of Geertsema, then the resulting valve would essentially be the Geertsema valve but with a circular top, which is nothing like the claimed invention.

In view of the foregoing, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,



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